

LPF plus FHA) in infants 5 to 11 months of age extremely important.¹⁸ Data on product-specific safety and efficacy will be needed for any product being considered for approval in the United States.

The results of the Swedish trial have been both helpful and perplexing. For the first time, evidence of the efficacy of a licensed Japanese vaccine has been shown in a placebo-controlled trial among infants, and for the first time a detoxified LPF alone was shown to be effective in children. However, the estimates of efficacy from this "gold standard" trial were less than those previously reported with whole-cell vaccines, although the later studies were not as methodologically rigorous and a true direct comparison is not possible and, if made, may be misleading. A direct comparison would have required using a whole-cell vaccine in the Swedish trial. Also, in contrast to the multidose schedules currently recommended in Japan and the United States, a two-dose schedule was adopted in Sweden based on immunogenicity studies in which levels of antibody thought to be protective by the investigators were achieved after two doses separated by an interval of two months.¹⁹ A third dose could potentially have raised efficacy estimates. Further, as noted by Cherry and associates, the failure to correlate serum antibody levels with protection against disease makes testing of other vaccines as well as monitoring quality control difficult and suggests there is a need for further study.

Additional data on safety and efficacy, as defined in studies of households, continue to be generated in Japan. These, combined with the efficacy data obtained from infants in Sweden, may result in an application for licensure in the United States of one or more acellular vaccines. Safety and serologic data are being obtained by different manufacturers for other types of products as well. The adequacy of the total body of data submitted in support of any license application must await a formal review by the Food and Drug Administration and their advisory groups. In the meantime, additional well-controlled studies, particularly comparative efficacy studies of whole-cell and different acellular vaccines, should be vigorously pursued. Until new vaccines are licensed, we will continue to need whole-cell vaccines. We can control the disease with the present vaccine, but until we have a vaccine that can be used in persons older than 6 years, we can expect to see continuing limited outbreaks of pertussis.

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A Critical Moment in Our History

AS A NATION we seem now to have lived through eight years of what some might call a time of wishful thinking, something akin to a pleasant dream. Any unpleasantness was largely ignored, or in a sense swept under the rug. We seemed actually to put our faith in the fantasy rather than in any reality of "star wars," as the Strategic Defense Initiative was dubbed. And at the end of the eight years, the polls showed almost unprecedented public approval of the way the Presidency had been conducted, and the electorate confirmed or even strengthened the political status quo. It appears that the Republicans continue to have a relatively secure hold on the White House and the Democrats have gained what seems to be almost permanent control of the Congress.

For better or worse, a major and enormously expensive commitment of national resources was made to assure that our nation would be militarily strong, and perhaps a fear that the Soviets could not compete either economically or militarily may have changed the minds of the Kremlin leadership and caused them to alter their policy of confrontation with the nations of the western world. This was a very major gain and possibly even worth the cost. But there has been a downside to this eight years of studied optimism and of military and political achievement. As a nation we have been losing ground to our own economic competitors in the western world, and there is disturbing evidence that our standard of living is not what it was even a few years ago. Servicing the national debt, the continuing federal budget deficits, a negative balance of international payments, and a growing foreign investment in American business and industry, are beginning to take their toll. These, together with the entitlement programs that we have voted to ourselves, have seriously constrained, if not diverted, resources that might now otherwise be available for domestic needs and to prepare us for the even harsher economic competition that may surely be expected in the very near future.

If harsher competition is what lies ahead for us as a nation, as is likely, we must give serious attention to girding ourselves and strengthening our resources for this purpose. The need for adequate education for every citizen seems obvious. We must all at least be literate, perhaps even computer literate. But equally important, and perhaps even more important, no nation can be truly strong unless it is also a healthy nation, and here too there is evidence that we are falling behind, in spite of our acknowledged scientific and technologic leadership in medical care. Many of our youth, particularly our disadvantaged youth, are not receiving either the education or health care they will need to compete successfully in our own society, not to mention to help pro-

vide the sinew to make our nation strongly competitive with the rest of the world.

This is truly a critical moment; it could even be a watershed moment in our history. Four or eight years from now may be too late. This is a time for a new realism, and for the kind of collaborative effort among all segments of society that happens best when a country perceives that it is in danger. And there is reason to believe that this nation is now in danger, albeit a different kind of danger than we have known in the past. Education and health, particularly of our youth, are lasting measures of power, and both surely should be top priorities for the new administration.

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